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| PRE-APPEAL BRIEF REQUEST FOR REVIEW | | Docket Number (Optional) MPD-002.01 | |
| | Application Number 10/702,189 | Filed Nov. 5, 2003 | |
| | First Named Inventor Dennis, William G. | | |
| | Art Unit 3731 | Examiner Nguyen, Tuan Van | |
| <p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> | | | |
| I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) <input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>48,543</u> <input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number _____ | | <u>/SCOTT E. KAMHOLZ/</u> Signature <u>Scott E. Kamholz</u> Typed or printed name <u>617-832-1176</u> Telephone number <u>August 25, 2008</u> Date | |
| <input type="checkbox"/> *Total of _____ forms are submitted. | | | |

Applicant's Memorandum in Support of the Pre-Appeal Brief Request for Review

The Examiner has rejected all pending claims (1-15 and 60-70) under 35 U.S.C. § 103(a) as reciting subject matter unpatentable over U.S. Pat. No. 6,193,732 to Frantzen et al. ("Frantzen") in view of U.S. Pat. No. 3,797,076 to Watkin ("Watkin").

The Examiner's rejection should be reversed because it is plainly wrong.

The rejected claims are directed to occlusion clips requiring (among other things) that the distal tips ("clip guides") of a clip be wider than the rest of the clip. The widened clip guides slide up on recessed rails in the jaws of a clip applier and then snap together when pushed past the rails' termination (see Figs 15-16 and specification paragraph [0058] of the present application).

The Examiner acknowledged that the tips of Frantzen's clips are not taller¹ than the rest of the clip but took the view that such a modification would have been obvious, as evidenced by the wide lips of Watkin's clothes clip.

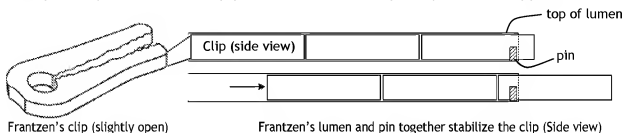
However, Frantzen teaches away from such a modification, and hence the claimed invention, because it would render the Frantzen clip unsuitable for its intended purpose. Frantzen's clip and clip applier are best shown in Figs. 19A-B and described in cols. 17-18. As Frantzen unambiguously states in lines 6-10 of col. 17:

Surgical clip 570 has a sufficiently small clearance within central lumen 620 such that the entire line of clips may be pushed in the direction of arrow 637 without the clips becoming misaligned or jamming within central lumen 620.

This disclosure means that the height of Frantzen's clip (when oriented sideways) must so closely match the tube's height that the clips can't tilt up or down; otherwise, advancing the clip row would tend to make the clips pitch into the tube walls and buckle with respect to one another. Frantzen prevents the tilting by closely matching the clip dimensions to those of the lumen. The low clearance between his lumen and clip also allows Frantzen to dispense with external guides for the clip, a

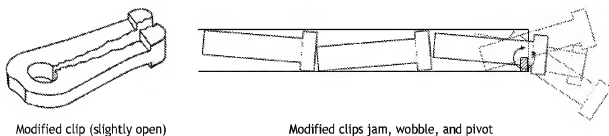
¹ "Widths" as recited in the rejected claims correspond to heights in Frantzen, because Frantzen's clip arms are illustrated as lying side-by-side, while the claimed clips' arms overlies one another.

feature he touts as a significant advantage of his design to improve endoscopic visibility (col. 2, lines 17-19 and 31-32; col. 18, lines 5-8). So as Frantzen's user advances the clip from the applier, the lumen's walls and pin work together to hold the clip steady, even as the clip protrudes almost completely from the applier:



Frantzen's clips therefore *must be flat*. His flat clips and small-clearance lumen fit hand-in-glove by express design. Yet the Examiner proposes to modify Frantzen's clip in view of Watkin by making the tips taller than the rest of the clip. Such a modification would be fundamentally at odds with Frantzen's system because it would destroy the "small clearance" Frantzen expressly calls for and would directly result in tilting, buckling, and wobble, *the very problems that Frantzen expressly seeks to solve*.

A clip so modified would resemble the illustration below, and, as immediately apparent, would undermine Frantzen's design principles.²



Because the lumen must accommodate the tall front end, the back end would fit loosely within the applier lumen, and the clips would be free to jiggle. And when the row of clips is pushed from behind, the natural reaction of the clips will be to

² The "modified" illustrations are creations of the undersigned attorney prepared for purposes of argument; they do not constitute an admission that such modification is obvious or even realizable from Frantzen's disclosure.

buckle in order to relieve the compression, thereby pitching up or down and jamming into the lumen wall.

Moreover, once the tall part of the clip has emerged from the free end of Frantzen's clip applier, *nothing holds the narrow clip back-end inside the applier's tall lumen*, except perhaps pin 595. But that pin's grip is insufficient to keep the pin steady in the lumen; even worse, it will act as a pivot point for the narrow clip to wobble within the lumen. Such wobble, of course, needlessly complicates the already challenging task of maneuvering a clip onto a blood vessel during laparoscopic surgery. Even a light bump against an anatomic structure could dislodge a "modified" clip with a springy snap that sends it flying anywhere inside the patient's abdomen.

There is no way to fix the problem the Examiner's modification creates without complicating Frantzen's design in just the ways from which Frantzen teaches away, such as by adding jaws or other external stabilizing mechanisms that will impair visibility. For this reason, Frantzen's disclosure teaches away from heightened tips, such as those shown in Watkin, and also away from the claimed clips, because *they simply will not work* in Frantzen's device.

The Examiner's comments in the Advisory Action do not answer or dispel these concerns; even if the proposed modification could somehow improve stability in one axis (though clearly not the "longitudinal axis" the Examiner names, or any other as far as Applicant can tell), it would reduce the overall stability of the clips to the point of uselessness. Moreover, Frantzen already achieves all the stability he deems necessary with his flat clips that fit snugly in the lumen; the Examiner's proposed modification undermines Frantzen's simple design for no purpose and no benefit.

The rejection therefore lacks an essential element required to establish a *prima facie* case of obviousness: a rationale for combining the references. The Supreme Court of the United States affirmed the need to show a rationale to combine or modify in an obviousness rejection, a need the Office acknowledged in formulating its new obviousness examination guidelines.³ Applicant has shown that, in fact,

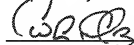
³ *KSR Int'l v. Teleflex*, 550 U.S. ___, ___, 82 U.S.P.Q.2d 1385, 1396, slip op. at 14 (US 2007).

Frantzen teaches away from Watkin and the claimed subject matter. Thus, the references themselves actively dissuade one of ordinary skill in the art from making the combination.

The teaching away is so glaring and so elementary that the panel should immediately appreciate that the rejection is fundamentally unsound. Accordingly, Applicant asks the panel to reconsider and withdraw the obviousness rejection of claims 1-15 and 60-70. Alternatively, Applicant asks the reviewing panel to suggest any amendments it feels would place the claims in condition for allowance.

Dated: August 25, 2008
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Respectfully submitted,



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